NDA 20-762/S-009

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Mary Jane Nehring
Director, Marketed Products Support

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated September 12, 2000, received September 13, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate) Nasal Spray.

This "Changes Being Effected" supplemental new drug application provides for the addition of anaphylaxis and angioedema to the post-marketing surveillance information in the ADVERSE REACTIONS section of the package insert.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted September 12, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. David Hilfiker, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research